NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RUTH E. STRONTZER, Plaintiff, v. **JOHNSON & JOHNSON,** ***et al.,*** Defendants.	Civil Action No. 20-10160 (ZNQ) (TJB) **OPINION**

QURAISHI, District Judge

This matter comes before the Court upon Defendants Mentor Worldwide LLC, Ethicon, Inc., and Johnson & Johnson's ("Defendants") Motion to Dismiss under Rule 12(b)(6). (ECF No. 38.) Alongside the Motion, Defendants submitted a Memorandum in Support. ("Moving Br.," ECF No. 38-1.) Plaintiff Ruth E. Strontzer ("Plaintiff") filed an Opposition. ("Opp'n Br.," ECF No. 39.) In response, Defendants filed a Reply. (ECF No. 40.) The Court has carefully considered the parties' submissions and decides the matter without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the following reasons, Defendants' Motion will be GRANTED IN PART and DENIED IN PART.

I. BACKGROUND AND PROCEDURAL HISTORY[1]

The parties are familiar with the factual background of this matter. Accordingly, the Court will limit its recital to the relevant history.[2]

In August 2009, Plaintiff had breast cancer. (Second Amended Complaint ("SAC") ¶ 36, ECF No. 35.) In December 2009, Plaintiff underwent bilateral mastectomies and reconstruction with tissue expanders. (*Id*.) Following chemotherapy and left-breast radiation, Plaintiff exchanged the expanders for 700 cc Mentor Siltex breast implants. (*Id*.) In 2014, Plaintiff developed seroma in her left breast and had her left implant replaced with another Mentor Siltex implant. (*Id*. ¶ 37.) In July 2018, Plaintiff tested positive for BIA-ALCL. (*Id*. ¶ 38.) Following diagnosis and treatment, Plaintiff also suffered from a benign tumor in her salivary gland which was removed. (*Id*. ¶ 43.) At the time the Mentor implant was placed into Plaintiff's body, "she was not advised, nor did she have any independent knowledge, that the Implants were associated with or known to cause ALCL" (*Id*. ¶ 44) and, according to Plaintiff, had she "been advised that implantation was associated with even the slightest risk of developing ALCL and/or BIA-ALCL she would not have proceeded with implantation of the Implants" (*Id*. ¶ 48.)

On August 7, 2020, Plaintiff filed an initial Complaint. (ECF No. 1.) On September 10, 2020, Plaintiff filed the First Amended Complaint ("FAC"). (ECF No. 5.) The FAC alleged a violation of the Connecticut Products Liability Act ("CPLA"), Conn. Gen. Stat. §§ 52-572m, *et seq*., based on a series of separate theories: manufacturing defect, breach of express and implied warranties, failure to provide warnings, negligent manufacturing, and negligent misrepresentation.

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[1] For the purposes of this motion, the Court assumes as true the facts alleged in the Complaint. *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008).

[2] For a full recitation of the factual background regarding breast implants and Breast Implant-Associated Large Cell Lymphoma ("BIA-ALCL"), the Court refers the parties to its March 31, 2021 Opinion. *See D'Addario v. Johnson & Johnson*, Civ. No. 19-15627, 2021 WL 1214896 (D.N.J. March 31, 2021).

(FAC ¶¶ 220–303). Thereafter, Defendants filed their first Motion to Dismiss the FAC. (ECF No. 8.) On March 31, 2021, the Court granted the Motion, and permitted Plaintiff one more opportunity to amend her pleading. (ECF No. 34.) Critically, the Court relied upon the reasons identified in a parallel case before the Court that involved the same products and same Defendants: *D'Addario v. Johnson & Johnson*, Civ. No. 19-15627. (*Id.*) (citing 2021 WL 1214896 (D.N.J. March 31, 2021) (*"D'Addario I"*)).[3]

On May 10, 2021, Plaintiff filed her Second Amended Complaint in this case. (ECF No. 36.)[4] Defendants responded with the current Motion.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows a court to dismiss an action for failure to state a claim upon which relief can be granted. In deciding a 12(b)(6) motion to dismiss, a district court is "required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff]." *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Twombly*, 550 U.S. at 570. "Detailed factual allegations" are not required, but the

[3] In *D'Addario* different plaintiffs sued the same defendants, alleging identical violations of the CPLA under the theories of manufacturing defect, breach of implied warranties, failure to provide warnings, negligent manufacturing, and negligent misrepresentation theories. 2023 WL 239395, at *2 (D.N.J. Jan. 18, 2023) ("*D'Addario II*"). Additionally, the plaintiffs in *D'Addario* alleged a loss of consortium claim against defendants. *Id*. In the Court's most recent Opinion in that case, the Court denied the defendants' Motion to Dismiss plaintiffs' CPLA violations under the theories of manufacturing defect, negligent manufacturing, breach of implied warranties, and failure to provide warnings. *Id*. at *10. The Court, however, granted defendants' Motion and dismissed with prejudice the plaintiffs' negligent misrepresentation claim under the CPLA. *Id*.

[4] The Court agrees with Defendants, that Plaintiff's SAC is nearly identical to the operative Complaint in *D'Addario*. (Moving Br. 20; ECF No 38-5, attached as Ex. C.)

complaint must include "factual enhancements" and not mere conclusory statements or a recitation of the elements of a cause of action. *Id*. at 557.

III. JURISDICTION

Given the citizenship of the parties and the amount in controversy, the Court finds that it has diversity jurisdiction over this matter pursuant to 28 U.S.C. § 1332.

IV. DISCUSSION

The Connecticut Product Liability Act, CPLA, defines a product liability claim to include "all claims or actions brought for personal injury . . . or property damage caused by the manufacture, ... design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product." Conn. Gen. Stat. § 52–572m(b).

Defendants contend that Plaintiff's claims pursuant to the CPLA are preempted by federal law. (Moving Br. at 6.) Defendants argue that despite Plaintiff's effort in adding facts to the SAC, the allegations do not address the deficiencies the Court noted in *D'Addario I*, and that Plaintiff's claims remain preempted. (*Id*. at 4.) In Opposition, Plaintiff argues that the SAC cures such deficiencies, and alleges claims that are grounded in traditional state-tort law. (*See generally* Opp'n Br.)

A. Federal Preemption

It is undisputed that the Mentor Breast Implants are a Class III medical device approved by the FDA under the premarket approval process outlined by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). (SAC ¶ 29.) "Before marketing a Class III medical device, the manufacturer must submit a PMA application that the FDA can grant 'only after it determines that a device offers a reasonable assurance of safety and effectiveness." *In re Allergan Biocell Textured Breast Implant Prods. Liability Litig.*, Civ. No. 19-2921, 2021 WL

1050910, at *7 (D.N.J. Mar. 19, 2021) (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) (citing 21 U.S.C. § 360e(d))). "A state law product liability or tort claim relating to a medical device may be expressly or impliedly preempted by the MDA," which "contains a broad express preemption provision." *Id*. (quoting *Shirker v. Smith & Nephew, PLC*, 885 F.3d 760, 767 (3d Cir. 2018)). "The MDA provides that no State 'may establish or continue in effect with respect to a device ... any requirement relating to safety or effectiveness that is different from, or in addition to, federal requirements." *Riegel*, 552 U.S. at 328 (quoting 21 U.S.C. § 360k(a)).

The Supreme Court has recognized, however, a narrow exception for a "parallel claim, e.g., a damages remedy for claims premised on a violation of FDA regulations." *Clements v. Sanofi-Aventis*, U.S., Inc., 111 F. Supp. 3d 586, 600 (D.N.J. 2015) (quoting *Riegel*, 552 U.S. at 330). To determine whether the MDA expressly preempts a state claim under § 360k(a), courts consider (1) whether the FDA has established "requirements" applicable to the specific device at issue; and if so, (2) whether the plaintiff's claims are based on state requirements that are "different from, or in addition to," the federal ones and that "relate to safety and effectiveness." *Shirker*, 885 F.3d at 771 (citing *Riegel*, 552 U.S. at 321–22). If the answer is yes to both questions, the state claim is preempted. *Id*. "If, instead, the answer to the second question is no, then the state duties in such a case parallel, rather than add to, federal requirements, and the claims are not preempted." *Id*. (citation omitted) (internal quotation marks omitted).

Even if a state-law claim is not expressly preempted, it may be impliedly preempted under § 337(a). Under the MDA, all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). "[T]he Federal Government rather than private litigants . . . are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). To that end, the *Buckman* Court

held that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives" and are impliedly preempted by the MDA. *Id*. at 350.

Ultimately, where a state-law claim for violating a state-law duty "parallels" a federal-law duty under the MDA, the MDA will not preempt the state-law claim. *Riegel*, 552 U.S. at 330. It is not enough to contend that a state law parallels federal law generally. Plaintiffs must also allege a link between a product's deviation from an FDA requirement and the alleged injury. *Clements*, 111 F. Supp. 3d at 598; *see Simoneau v. Stryker Corp.*, Civ. No. 13-1200, 2014 WL 1289426, at *10 (D. Conn. Mar. 31, 2014) (dismissing a plaintiff's misbranding, failure to warn, and failure to report claims for failure to link her injury to a violation of an FDA requirement).

While Mentor's MemoryShape breast implants are Class III medical devices subject to PMA and federal requirements, Mentor's CPX4 tissue expanders are non-PMA devices, and are sold through the § 510(k) process that does not trigger preemption. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996).

The Court next considers Plaintiff's claims within the foregoing legal framework.

B. Manufacturing Defect (Count I(A))

To recover on a theory of strict liability under the CPLA, a plaintiff must show that the device was in a defective condition unreasonably dangerous to the claimant and that this defect caused the injury for which the complainant seeks damages. *D'Ascanio v. Toyota Indus. Corp.*, 309 Conn. 663, 674 (2013) (citation omitted); *Izzarelli v. R.J. Reynolds Tobacco Co.*, 731 F.3d 164, 168 (2d Cir. 2013) (applying strict liability doctrine in CPLA action). "A product may be defective due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions." *Vitanza v. Upjohn Co.*, 257 Conn. 365, 373 (2001). In this context, "[t]o sufficiently plead a manufacturing defect claim, [p]laintiffs must allege [defendants] deviated

from a particular premarket approval or other FDA requirement applicable to the class III medical device." *In re Allergan*, 2021 WL 1050910, at *20.

Here, Defendants argue that the SAC fails to demonstrate how the process used to manufacture Plaintiff's implants deviated from the process approved by the FDA. (Moving Br. at 7.) Defendants contend that, if anything, Plaintiff alleges a design defect, rather than a manufacturing defect. (*Id*.) Moreover, Defendants criticize Plaintiff's allegations as conclusory, and failing to identify a specific regulatory violation. (*Id*. at 9.)

Like in *D'Addario*, here the SAC in this case pleads that by "failing to sterilize the implants in conformance with the PMA, failing to satisfy the study and follow-up requirements set forth in the PMA and other federal requirements, failing to maintain procedures to prevent contamination of equipment or products, and failing to timely and accurately submit adverse event reports on the occurrences of BIA-ALCL," Defendants violated the federal requirements because the breast implants contained unintended manufacturing debris. (SAC ¶ 257.); *D'Addario I,* 2023 WL 239395, at *5(D.N.J. Jan. 18, 2023.) Moreover, the SAC pleads that this failure resulted in serious injuries to Plaintiff. (SAC ¶ 262.) Again, this Court concludes that Plaintiff has plausibly pled that the product was defective and that the defect existed when the product left the manufacturer's control. *Bifolck v. Philip Morris, Inc.*, 324 Conn. 402, 434 (2016). Accordingly, the Court finds that the SAC sufficiently alleges that the implants and tissue expanders contained a manufacturing defect. This part of the Motion to Dismiss will therefore be denied.

C. Negligent Manufacturing (Count I(D))

Moreover, like in *D'Addario*, Plaintiff alleges that Defendants negligently manufactured the Siltex implants by "not controlling the texturing process leaving residual silicone and polyurethane particles, debris and fragments from the textured elastomer shell on the implant

surface." (SAC ¶ 305.) As this Court previously observed, "negligent manufacturing is not preempted, because to the extent such negligence is premised on a violation of FDA requirements, the state common law duty parallels the federal requirement." *D'Addario II*, 2023 WL 239395, at *5 (citations omitted.) Accordingly, the Court concludes that Plaintiff's negligent manufacturing claims as to the MemoryShape are also not preempted. Therefore, the portion of Defendants' Motion seeking to dismiss Count I(D) will be denied.

D. Breach of Implied Warranty (Count 1(B))

Plaintiff alleges a breach of implied warranty under the CPLA. (SAC ¶ 267–281.) "State law claims for breach of implied warranty may be preempted to the extent that they impose new or additional requirements on manufacturers beyond the federal regulations governing the medical device at issue." *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 356 (D. Del. 2019) (citations omitted). But a state law claim for breach of implied warranty is "viable," "to the extent [it] seek[s] recovery for conduct that may also have violated the FDCA." *In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 781, 792 (3d Cir. 1999).

Here, the parties agree that Plaintiff's manufacturing defect claim also forms the basis for her implied warranty claim. (Moving Br. at 9; Opp'n Br. at 38.) Insofar as the Court has determined that Plaintiff has adequately pled a manufacturing defect claim, *supra*, it further finds that Plaintiff's breach of implied warranty claim is also viable and not preempted. *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 166 (S.D.N.Y. 2011) (finding the plaintiffs' implied warranty claim not preempted because it was based on their manufacturing defect claim, for selling an adulterated device makes the product unfit for its ordinary purpose)); *see also Bass*, 669 F.3d at 517 ("We agree . . . that an implied warranty claim is not preempted if the plaintiff alleges that the defendant violated federal requirements and can ultimately show a causal link between the

violation and the breach of the implied warranty."). Accordingly, the portion of the Motion seeking to dismiss Plaintiff's implied warranty claim will be denied.

E. Negligent Misrepresentation (Count I(E))

Under Connecticut law, to state a claim for negligent misrepresentation a plaintiff must establish "(1) that the defendant made a misrepresentation of fact (2) that the defendant knew or should have known was false, and (3) that the plaintiff reasonably relied on the misrepresentation, and (4) suffered pecuniary harm as a result." *United Rentals, Inc. v. Wagner*, Civ. No. 07-519, 2008 WL 2167021, at *3 (D. Conn. May 22, 2008). The Court is again guided by its reasoning in *D'Addario II*.

In *D'Addario II*, the Court observed that the plaintiffs alleged defendants "knowingly made negligent misrepresentations of fact by selling its [breast implants] that were defectively manufactured as if they were manufactured pursuant to all federal specifications." *See* 2023 WL 239395, at *5. Further, the plaintiffs alleged that defendants "deliberately concealed or failed disclose" the associated risks. *Id*. The Court found that the plaintiff's pleading of a negligent misrepresentation claim was "couched in fraud like terms," such that heightened pleading standard applied. *Id*. at *6. Accordingly, the Court applied the pleading standard of Rule 9(b)[5], and found that while the plaintiffs alleged that defendants acted fraudulently in misrepresentation, plaintiffs fail to specify statements made by defendants that were "fraudulent, identify the speaker, state where and when the statements were made, and explain why the statements were fraudulent." *Id*. at 7.

[5] Courts disagree about whether the heightened pleading standard of Rule 9(b) applies to negligent misrepresentation claims. *See ARMOUR Capital Mgmt. LP v. SS&C Techs., Inc.*, Civ. No. 17-790, 2018 WL 1368908, at *6 (D. Conn. Mar. 16, 2018) (describing the disagreement). However, courts do agree that when "negligent misrepresentation is couched in fraud-like terms of known falsity," the heightened fraud pleading standard applies. *See Karazin v. Wright Med. Tech., Inc.*, Civ. No. 17-823, 2018 WL 4398250, at *7 (D. Conn. Sept. 14, 2018); *ARMOUR Capital, Mgmt. LP v. SS&C Techs., Inc.*, Civ. No. 17-790, 2020 WL 64297, at *2 (D. Conn. Jan. 5, 2020).

Here, Plaintiff alleges that by "[s]elling the SILTEX implants as fully compliant with FDA requirements when in fact they were manufactured with defects is misrepresentation." (SAC ¶ 322.) Plaintiff again asserts that Defendants "negligently misrepresented material information regarding their Breast Implants, namely, that they were manufactured according to required specifications." (*Id.* ¶ 321.) Thus, Plaintiff chiefly relies upon her assertion that Defendants did not comply with required specifications. Unfortunately, failing to disclose a risk by not complying with the reporting regulations or federal disclosure requirements does not satisfy the standard required to plead a claim for negligent misrepresentation. *See Norman v. Bayer Corp.*, Civ. No. 16-253, 2016 WL 4007547, at *6 (D. Conn. July 26, 2016) (dismissing negligent misrepresentation claim as preempted where "plaintiff does not identify any statement that is outside what was approved by the FDA"). Further, Plaintiff's SAC fails to plead any statements that were made by Defendants that were not approved by the FDA. *Hart v. Medtronic, Inc.*, Civ. No. 16-05403, 2017 WL 5951698 at *4, (D.N.J. Nov. 30, 2017) (finding that to the extent these statements were not approved by the FDA, they accordingly are not preempted.); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 827 (E.D. Pa. 2016) (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (finding that parallel misrepresentation claims are cognizable when it is alleged that [the defendant] made statements that were "inconsistent with specific statements in approved FDA materials.") Accordingly, Plaintiff's negligent misrepresentation claim will be dismissed with prejudice.[6]

[6] To be clear, the Court's reaches its conclusion by assessing the negligent misrepresentation against the pleading requirements of Rule 8 rather than the heightened standard of Rule 9(b) because the Court finds that Plaintiff's pleading is not "couched in fraud like terms" that would invoke the latter standard.

F. Failure to Warn (Count I(C))

Courts evaluating a failure to warn claim engage in a three-step analysis. *See Karavitis v. Makita U.S.A., Inc.*, 243 F. Supp. 3d 235, 252–53 (D. Conn. 2017.) First, a plaintiff must satisfy the five elements governing all product liability, and demonstrate that: (1) the defendant was engaged in the business of selling the product; (2) the product was in a defective condition unreasonably dangerous to the consumer or user; (3) the defect caused the injury for which compensation was sought; (4) the defect existed at the time of the sale; and (5) the product was expected to and did reach the consumer without substantial change in condition. *Id*. at 249. Second, the plaintiff must show that product instructions or warnings "were required, and if so, whether they were adequate." *Id*. In that determination, the following factors are relevant: "(1) [t]he likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions." *Id*. at 252–53 (citing Conn. Gen. Stat. § 52-572q(b)). Third, a plaintiff must establish that "if adequate warnings or instructions had been provided, the claimant would not have suffered the harm." *Id*. at 253 (quoting Conn. Gen. Stat. § 52-572q(c)).

"Under the CPLA, a product seller is liable for a plaintiff's injuries when a product lacks adequate warnings directed to the person best positioned to keep the plaintiff from being hurt, and if the plaintiff would not have been injured if the warnings had been provided." *Klorczyk v. Sears, Roebuck & Co.*, Civ. No. 2019 WL 1433645, at *13 (D. Conn. Mar. 29, 2019) (citing Conn. Gen. Stat. § 52-572q). "Warnings must specifically identify for the user the danger inherent in the product's use." *Id*. at *14 (quoting *Giglio v. Conn. Light & Power Co.*, 180 Conn. 230, 237 (1980)); *see also Fraser v. Wyeth, Inc.*, 992 F. Supp. 2d 68, 81 (D. Conn. 2014) (An overly broad or

confusing warning will not suffice to discharge a prescription drug manufacturer's duty to adequately warn a prescribing physician, *De Souza v. TAP Pharm., Inc.*, Civ No 3-2247, 2006 WL 1328754, *1 (D. Conn. Jan. 3, 2006), nor is the mere mention or equivocal reference to a particular injury sufficient, *see Thom v. Bristol–Myers Squibb Co.*, 353 F.3d 848, 853 (10th Cir. 2003.)

Defendants argue that Plaintiff's failure to warn claim should be dismissed because Mentor did not have a duty to warn of BIA-ALCL until at least 2011. (Moving Br. at 12.) Moreover, Defendants contend that Plaintiff does not plead facts showing that the FDA would have included any additional adverse events in its database had Mentor reported them, nor does Plaintiff sufficiently allege that her physician even relied on information in the FDA database when making his treating decisions. (*Id*. at 18–19.)

In Opposition, Plaintiff appears to recharacterize her failure to warn claim as a failure to test claim. (Opp'n Br. at 36.)[7] Unfortunately, Plaintiff cannot amend her Complaint via her brief. *Pennsylvania ex rel. Zimmerman v. Pepsico*, Inc., 836 F.2d 173, 181 (3d Cir. 1988) ("It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.") The Court is bound to accept the allegations of the SAC as Plaintiff's operative pleading.

[7]Connecticut law recognizes negligent failure to test as a basis for product liability independent from failure to warn. "The definition of products liability, § 52–57m(b) covers damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling any product." *Bogrette v. Clark Equipment Co.*, Civ. No. 97–0258940S, 1998 WL 252354, at *5 (Conn. Super. Ct. May 8, 1998) (noting that the plaintiff's products liability claim was based on the defendants' "failure to give warning of the dangerous propensities as designed, manufactured or distributed as well as defendant Clark's failure to test and design when defendant knew or should have known of the forklift's potential danger"); *see also Beers v. Bayliner Marine Corp.*, 236 Conn. 769, 772, 675 A.2d 829 (1996) ("The plaintiffs claim that their injuries were caused by the defective condition of the boat, and that the defendant is liable for their injuries under, inter alia, product liability theories of manufacturing defect, design defect, failure to warn of those defects and failure to test adequately the boat."). *Cf. Densberger v. United Technologies Corp.*, 297 F.3d 66, 70–71 (2d Cir. 2002) (manufacturer has continuing duty to study and warn consumers).

On the issue of failure to warn, the Court is again guided by its recent decision in D'*Addario II*. The threshold question regarding Plaintiff's failure to warn claim is whether as pleaded it sufficiently satisfies the aforementioned elements. First, Plaintiff alleges that Defendants were engaged in the business of selling the product (SAC ¶ 4); (2) the product was in a defective condition unreasonably dangerous to the consumer or user (*Id*. ¶¶ 2–3); (3) the defect caused the injury for which compensation was sought (*Id*. ¶ 225); (4) the defect existed at the time of the sale (*Id*. ¶ 251); and (5) the product was expected to and did reach the consumer without substantial change in condition (*Id*. ¶ 252). *Karavitis*, 243 F. Supp. 3d at 252. Next, Plaintiffs sufficiently allege that warning labels were required (SAC ¶¶ 283–92), and not provided to the person best positioned to keep the plaintiff from being hurt (*Id*. ¶ 287). *Karavitis*, 243 F. Supp. 3d at 252. Lastly, Plaintiffs allege that "if adequate warnings or instructions had been provided, the claimant would not have suffered the harm" (SAC ¶ 300); *Karavitis*, 243 F. Supp. 3d at 252. Based on these allegations, the Court finds that the SAC pleads a plausible claim for failure to warn under the CPLA. Accordingly, this portion of Defendants' Motion will be denied.

V. CONCLUSION

For the foregoing reasons, the Court will GRANT the portion of the Motion seeking to dismiss Plaintiff's negligent misrepresentation claim and dismiss the negligent misrepresentation claim with prejudice. The Court will DENY the remainder of the Motion that seeks to dismiss

Plaintiff's claims for manufacturing defect, negligent manufacturing, breach of implied warranty, and failure to warn. An appropriate Order will follow.

Date: **May 22, 2023**

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE